REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 18-19, 21-25, and 28-34 are pending in the present application. Claims 31 and 33 have been amended to recite a method for treating serotonin- or melatonin-mediated disorders. Claim 29 has been amended to recite a pharmaceutical composition suitable for the treatment of serotonin- or melatonin-mediated disorders. Support for amended claims 29, 31 and 33 may be found generally throughout the specification and in the original claims. In particular, support for the amended claims may be found in the present specification at page 5, line 3 to page 6, line 22.

In the outstanding Official Action, claims 16-30 were rejected under 35 USC §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants believe the present amendment obviates this rejection.

In imposing the rejection, the outstanding Official Action alleged that the present disclosure did not enable methods for preventing serotonin- or melatonin-mediated disorders.

However, as noted above, independent claims 31 and 33 have been amended to recite a method for treating serotonin- or melatonin-mediated disorders. Claim 29 has been amended to recite a pharmaceutical composition suitable for the treatment of serotonin- or melatonin-mediated disorders. As the claims are directed to the treatment of serotonin- or melatonin-mediated disorders and not the prevention of these disorders, applicants believe that the rejection has been obviated.

Thus, applicants believe that claims 18-19, 21-25, and 28-30 are enabled by the present disclosure.

In the outstanding Official Action, claims 29-30 were rejected under 35 USC §103(a) as allegedly being unpatentable over SERFONTEIN 5,631,271. Claims 16-28 were rejected under 35 USC §103(a) as allegedly being unpatentable over SERFONTEIN in view of PAUL et al. 5,292,538. On page 7 of the Official Action, it was stated that claims 31-34 were also rejected under 35 USC §103(a) as allegedly being unpatentable over SERFONTEIN in view of PAUL et al. These rejections are respectfully traversed.

Applicants believe that SERFONTEIN fails to teach each and every recitation of the claimed invention. SERFONTEIN teaches a pharmaceutical, veterinary, or dietary composition and the use thereof for a method of treatment or prophylaxis of depressed or inadequate intracellular pyridoxal phosphate levels in an individual resulting from a condition, wherein the

pyridoxine intracellular pyridoxal phosphate pathway is disturbed or insufficient. SERFONTEIN teaches the administration of vitamin B6, vitamin B12 and folic acid to prevent this disorder. The administration of these components is believed to result in the lowering of homocysteine levels, which have been linked to insufficient pyridoxine-pyridoxal conversion.

However, there is no known relationship between homocysteine levels and serotonin- or melatonin-mediated disorders. Indeed, the homocysteine metabolism is known to be largely concentrated in the liver, whereas serotonin- and melatonin-mediated affects are controlled by the brain. There is simply no recognition of treating serotonin- or melatonin-mediated disorders with the claimed composition. As a result, SERFONTEIN fails to provide any motivation or reasonable expectation of success of modifying its teachings to obtain the claimed invention.

Applicants believe that SERFONTEIN also teaches away from the recited amounts of the claimed invention. For example, SERFONTEIN teaches the administration of 0.04 mg (40 µg) of folate (folic acid) per infant per day (most preferred range: 20-100 µg/i/d). The dosage according to the claimed invention is more than 44 µg folate per 100 kcal per infant. The average energy intake by infants is around 100 kcal per kg per day. For a newborn of 3 kg, this corresponds to 300 kcal, i.e., more than

132 µg per infant per day, and substantially more for infants only a few months old. This is well above the amount proposed by SERFONTEIN.

Applicants further note that the US RDA for folate is about 400 µg per day for adults. Energy consumption for an adult, even when diseased or elderly, is around 1500 kcal per day or higher. Accordingly, folate would then be administered at a level of more than 660 µg per day or higher, well above recommended amounts. As a result, applicants submit that SERFONTEIN teaches away from the claimed invention.

In support of the rejection, the Official Action alleged that the use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose, even though results are better than expected. However, as noted above, SERFONTEIN is directed to an entirely different purpose. Indeed, none of the cited publications show a material or a class of materials that can be used in the treatment of serotonin- or melatonin-mediated disorders.

In an effort to remedy the deficiencies of SERFONTEIN, the outstanding Official Action cites to PAUL et al. However, PAUL et al. teach the administration of a blend of sugars and proteins together with magnesium for anabolic use. The composition is designed to improve physical conditions such as

muscle catabolism and negative energy balance (see column 1, lines 15-26). These conditions are also unrelated to serotonin- and melatonin-mediated disorders.

While a broad vitamin mixture is suggested by PAUL et al., PAUL et al. teach that these components can be added to supplement and optimize the disclosed formulation for purposes of sustained energy and metabolism (column 7, lines 44-48). Thus, the publication does not provide the necessary motivation and a reasonable expectation of success of combining and modifying the cited publications to obtain a composition and method for treating serotonin- or melatonin-mediated disorders. Moreover, the amounts of the specific vitamins as described by PAUL et al. are low compared to the claimed invention.

The outstanding Official Action also alleged that applicants have not demonstrated any criticality or unexpected result which stems from the selection of specific vitamins lower in amounts than suggested by the cited publications. However, applicants do not believe that the Official Action has met its burden in showing that the claimed invention has been rendered obvious.

Moreover, the Examiner is respectfully reminded that a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the variable might

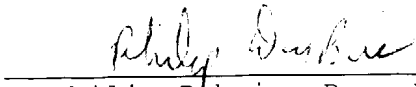
be characterized as routine and not given consideration. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). As to the cited publications, neither publication teaches a composition or method for treating serotonin- or melatonin-mediated disorders. There is no suggestion that the recited components may be simply optimized routine. In fact, none of the publications disclose or suggest a composition or method for treating serotonin- or melatonin-mediated disorders.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application is now in condition for allowance, with claims 18-19, 21-25, and 28-34, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



Philip Dubois, Reg. No. 50,696
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

PD/lk